Validation of a Filipino Translation of the Children's Dermatology Life Quality Index Text Version

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ABSTRACT

Background. Skin diseases that are longstanding or highly symptomatic can have devastating consequences in the quality of life of children. There is a need to have a validated Filipino translation of a dermatology quality of life tool for young patients with skin diseases.

Objectives. To assess the validity and reliability of the Indeks ng Kalidad ng Buhay Pang-dermatolohiya ng mga Bata (IKPaB), a Filipino translation of the Children's Dermatology Life Quality Index (CDLQI).

Methods. This cross-sectional study was conducted among children aged 4 to 16 years at a tertiary hospital outpatient department. The IKPaB was pretested and revised using focus group discussion until it was approved by the original developers for validation. Face validity was determined through cognitive debriefing interviews. Construct validity was determined by comparing IKPaB scores of participants with skin disease and without skin disease using Mann-Whitney U test. Criterion validity was determined by comparing IKPaB with a validated Filipino-translated PedsQL as the criterion, using Spearman rank correlation. Internal consistency reliability was determined using Cronbach's coefficient. Multiple regression was used to correlate age, sex and disease duration.

Results. The IKPaB was assessed to be comprehensible, clear, and culturally appropriate. Among 288 participants, it showed satisfactory construct validity (U = 8849, Z = 0.87; P = 0.89) and internal consistency reliability (α = 0.89), with a negative but weak correlation with the PedsQL® (rho = -0.300, P = 0.000).

Conclusion. The IKPaB is a valid and reliable Filipino translation of CDLQI. We recommend further validation for use in clinical practice and research.

Key Words: validation, validity, reliability, quality of life, children, CDLQI, Filipino CDLQI

INTRODUCTION

Skin diseases in children and adolescents, whether acute or chronic, can have significant consequences in their quality of life. Acne patients suffer from social, psychological and emotional problems that equal those reported by patients with chronic disabling medical conditions such as asthma, epilepsy, diabetes, back pain, and arthritis.12 In adolescents with atopic eczema, impaired quality of life correlate with depression, anxiety, and stress symptoms.3 Vitiligo in children has been associated with higher psychosocial dysfunction in the form of anxiety and depression.4

In 2017, more than a third of 5- to 16-year-old Filipino children were diagnosed with chronic skin diseases (acne vulgaris, 20.2%; and atopic dermatitis, 16.5%); while acute infectious diseases accounted for 7 in the top 10 (molluscum contagiosum, 14.3%; scabies, 12.1%; pediculosis capitis,
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OBJECTIVES

General Objective

To validate the IKPaB, a Filipino translation of the CDLQI text version.

Specific Objectives

1. To determine the face validity, construct validity, criterion validity and internal consistency, and reliability of IKPaB
2. To correlate the IKPaB scores with the age, sex, and duration of skin disease

METHODS

This two-part study was conducted according to a study protocol.

Ethical approval was given by the University of the Philippines Manila Research Ethics Board.

Setting and Study Population

This study was conducted at the University of the Philippines Manila-Philippine General Hospital (UPM-PGH) outpatient department from August 2013 to August 2014. Through convenience sampling, children aged 4 to 16 years were recruited with the following criteria: native speakers of Filipino; diagnosed with skin disease at the dermatology and pediatric outpatient clinics; or without skin disease who were accompanying adult patients at any clinic. The diagnosis of the latter group was based on (1) a negative answer to the question, “Do you have any skin problem that you want to consult about?” and (2) absence of pathologic skin lesions on physical examination.

Instrument

The instrument pre-tested was the “Indeks ng Kalidad ng Buhay Pang-dermatolohiya ng mga Bata” (IKPaB), a Filipino translation of the CDLQI text version. After obtaining permission from the original CDLQI developers, the translation was started in 2009 by Dr. Rowena Genuino (Communication, Genuino 2013), and was finally approved for pretesting in March 2013. The translation process followed the published guidelines on translation and cultural adaptation for patient-reported outcomes.

The IKPaB is self-explanatory and can be simply handed to patients aged 4 to 16 years. Like its original counterpart, IKPaB has 10 questions: 1 and 2, on symptoms and feelings you want to consult about?; 3 to 6, on effects of the skin condition on leisure; 7, on conflicts in school or holidays; 8, on effects of the skin condition on personal relationships; 9, on effects of the skin condition on schoolwork; and 10, on effects of the skin condition on sleep. The IKPaB is self-explanatory and can be simply handed to patients aged 4 to 16 years. Like its original counterpart, IKPaB has 10 questions: 1 and 2, on symptoms and feelings (Table 1).

Table 1. Weighted score per graded response

<table>
<thead>
<tr>
<th>Graded response (CDLQI)</th>
<th>Graded response (IKPaB)</th>
<th>Weighted Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very much</td>
<td>Sobra sobra</td>
<td>3</td>
</tr>
<tr>
<td>Quite a lot</td>
<td>Masyado</td>
<td>2</td>
</tr>
<tr>
<td>Only a little</td>
<td>Kaunti</td>
<td>1</td>
</tr>
<tr>
<td>Not at all</td>
<td>Hindi kailamman</td>
<td>0</td>
</tr>
<tr>
<td>Not applicable</td>
<td>Hindi naaangkop</td>
<td>0</td>
</tr>
<tr>
<td>Prevented school</td>
<td>Di nakapasok sa eskwela</td>
<td>5</td>
</tr>
</tbody>
</table>

*Response is for question 7.1 only
The total score is calculated by summing the individual scores of each question, resulting in a possible maximum score of 30 and a minimum of 0. The higher the score, the more effect the skin condition has on the patient’s life; hence, a poorer quality of life (Table 2).

### Table 2. Interpretation of total IKPaB scores

<table>
<thead>
<tr>
<th>Score</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No effect at all on patient’s life</td>
</tr>
<tr>
<td>2-6</td>
<td>Small effect on patient’s life</td>
</tr>
<tr>
<td>7-12</td>
<td>Moderate effect on patient’s life</td>
</tr>
<tr>
<td>13-18</td>
<td>Very large effect on patient’s life</td>
</tr>
<tr>
<td>19-33</td>
<td>Extremely large effect on patient’s life</td>
</tr>
</tbody>
</table>

### Informed consent/assent

After study objectives, as well as risks and benefits of participating in the study had been explained to the participants and parents of participants, informed consent was obtained. Participants aged 10-16 years old were also asked to sign an assent form, in addition to the informed consent signed by their parents. Verbal assent was obtained from children below 10 years old. Each enrolled participant was then given a participant code as reference.

### Study procedure

#### Part 1: Pre-testing of IKPaB

The IKPaB questionnaire was self-administered to participants. Participants who had difficulty in answering the questions were assisted by the parent, guardian, or primary investigator. Questions and choices were read by the parent, guardian, or primary investigator if the participants were not able to read by themselves. Face validity of IKPaB was assessed in terms of comprehensibility, unambiguity, and relevance to the Filipino context/culture; this was done through cognitive debriefing after the participants answered the questionnaire. Participants were interviewed through focus groups of 5-10 each and verbally asked to answer 9 questions—four questions regarding the general instruction and impression of the participant on the IKPaB; and five question on each of the ten items of IKPaB. All questions were answerable by “yes” or “no”. Items on the questionnaire were then revised depending on the cognitive debriefing interview results. Pre-testing was done until all items were acceptable to all the participants. Revisions to the translation were agreed upon by the investigators and the original instrument developers (Finlay et al). Corrections on remaining spelling, diacritical, grammatical, or other errors were done before the final translation was produced (Appendix). The study then proceeded to Part 2 after all items were acceptable and original instrument developers approved the final translation.

#### Part 2: Validity and reliability testing of IKPaB

A sample size of 120 per arm (patients with skin disease and without skin disease) was estimated (α = 0.05, power = 0.8, Cronbach alpha expected or required = 0.83). To account for a 20% non-participation rate, we recruited 288 participants.

### Administration of the IKPaB and Filipino PedsQL

The IKPaB questionnaire was self-administered using the same methods and scoring system as previously stated. Participants aged 5 to 16 years were asked to answer a second questionnaire: “PedsQL Kalidad ng buhay ng mga bata Imbentaryo,” a validated Filipino version of Pediatric Quality of Life Inventory (PedsQL) 4.0 Generic Core Instrument. It is used to measure health-related quality of life in healthy children and adolescents, as well as those with acute and chronic health conditions. Permission to use this study instrument was obtained from the developers.

The PedsQL 4.0 Generic Core Scales are intended for young children (ages 5 to 7), children (ages 8 to 12) and teens (ages 13 to 18). Each is composed of 23 items comprising of 4 dimensions: physical, emotional, social, and school functioning. Responses are in a 5-point Likert scale from 0 to 4. Items are reverse scored and linearly transformed to a 0–100 scale for standardized interpretation (Table 3). Scores of each item range from 0 to 100, with maximum total score of 2300. The higher the PedsQL score, the better the QOL.

### Table 3. PedsQL Kalidad ng buhay ng mga bata Imbentaryo weighted score per graded response

<table>
<thead>
<tr>
<th>Response</th>
<th>Weighted score</th>
<th>Extension of scoring scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hindi kilalanman</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Halos hindi kilalanman</td>
<td>1</td>
<td>75</td>
</tr>
<tr>
<td>Paminsan-minsan</td>
<td>2</td>
<td>50</td>
</tr>
<tr>
<td>Madalas</td>
<td>3</td>
<td>25</td>
</tr>
<tr>
<td>Halos lagi-lagi</td>
<td>0</td>
<td>4</td>
</tr>
</tbody>
</table>

### Data analysis

Participants who answered 80% of the questions in the IKPaB questionnaires and 50% of the questions in the PedsQL questionnaires were included in the analysis. Demographic and clinical profiles were compared using descriptive statistics. Construct validity of IKPaB was determined by correlating the median scores of participants...
with skin disease and those without skin disease using Mann-Whitney test. Criterion validity was tested by correlating the total IKPaB scores with total PedsQL scores using Spearman rank correlation. A correlation coefficient of ≥ 0.4 was considered satisfactory. Internal consistency reliability of IKPaB was determined using item-score and total score correlation with Cronbach’s α coefficient method. A reliability coefficient of ≥ 0.7 was considered satisfactory.

RESULTS

Part 1: Pre-testing

Face validity of IKPaB questionnaire was confirmed with five revisions after six pre-testing sessions. The median age of the participants was 10.2 years old (range, 4 to 16). The mean (SD) time to complete the IKPaB was 6.4 minutes (2.9; range, 3.6 to 8). Participants from the six pretesting sessions answered all items. Revisions to the IKPaB based on the answers and comments of the participants included: the use of more appropriate word choices; rephrasing to improve sentence construction, clarificatory statements; and an additional response option (for ‘not applicable’) since swimming and sports are not widely practiced among Filipino children.

The final IKPaB version was determined to be comprehensible, unambiguous, and relevant to the sociocultural context and was approved both by the instrument developer and investigators before proceeding to part 2 of this study.

Part 2: Validation of IKPaB

Study flow

The IKPaB questionnaire was administered to 288 participants: 144 with skin disease and 144 without skin disease. (Figure 1).

Characteristics of participants

There were no baseline differences as to age and sex of participants with skin disease (mean, 9.3 years, SD 4.0; females, 56.9%) and those without skin disease (9.2 years, 3.3; females, 52.1%). Majority of the participants with skin disease had an acute condition (duration less than 6 months) (86/144, 59.7%). Among the dermatologic diagnoses, majority (77/144, 53.5%) were infectious diseases (Table 4).

Results for validity and reliability

Face validity

The IKPaB was assessed to be comprehensible, unambiguous, and culturally relevant.

Figure 1. Study flowchart.
Construct validity
Participants with skin disease had a significantly higher median IKPaB score (9, IQR 3 to 13) compared to those without skin disease (1, IQR 0 to 1) (Mann–Whitney $U = 4242.5$, $Z = 8.67$; $P < 0.05$ two-tailed). Majority of the participants diagnosed with skin disease were affected by their disease (119/144, 82.6%) compared to only 55/144 (38.2%) of those without skin disease. Of those participants with skin disease, majority experienced small effect on QOL due to their skin disease (81/144, 55.6%) (Figure 2).

Criterion validity
There was a weak negative correlation between IKPaB and PedsQL (Spearman rank correlation rho = -0.30, $P = 0.00$). This indicates that as the score of IKPaB increases, the score of PedsQL decreases—which means a lower quality of life, although the correlation is weak.

Internal consistency reliability
There was satisfactory internal consistency reliability (Cronbach’s alpha coefficient, 0.87, 95% CI 0.85, 0.89).

Correlation of IKPaB with age, gender, and duration of skin disease
Participants with shorter duration of skin disease tended to have higher IKPaB scores (coefficient, -0.001); however, this was not statistically significant ($P = 0.14$). Similarly, age ($P = 0.79$) and sex ($P = 0.59$) were not significantly correlated to the IKPaB scores (Table 5).

Mean time to complete the questionnaires by both groups (with and without skin disease) was similar for IKPaB (4.5 mins) and PedsQL (4.6 mins) and within the acceptable time of 5 minutes. Response rate was 100%. All items in the IKPaB were answered by all the participants.

DISCUSSION
The IKPaB was shown to be a comprehensible, unambiguous, and culturally adapted translation of the CDLQI among Filipino children aged 4 to 16 years, with good face validity, construct validity ($Z = 8.67$; $P < 0.05$), and internal consistency reliability (Cronbach’s alpha = 0.87). However, criterion validity of IKPaB with PedsQL as the reference criterion was below satisfactory (rho = -0.30). The mean time to complete the IKPaB was 4.5 minutes. There was no correlation between IKPaB scores and predictor variables of gender, age, and duration of skin disease.

Table 4. Distribution of participants according to type of skin disease and duration of skin disease

<table>
<thead>
<tr>
<th>Duration of Skin Disease (n=144)</th>
<th>No. of participants (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute (&lt;6 mos.)</td>
<td>86 (59.7)</td>
</tr>
<tr>
<td>Chronic (&gt;6 mos.)</td>
<td>58 (40.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of Skin Diseases (n=148)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eczemas (contact dermatitis, atopic dermatitis, dyshidrotic eczema, nipple dermatitis, seborrheic eczema)</td>
</tr>
<tr>
<td>Genodermatoses (neurofibromatoses)</td>
</tr>
<tr>
<td>Infectious dermatoses (acute paronychia, arthropod bites, folliculitis, furunculosis, impetigo contagiosa, mycetoma, pediculosis capitis, pityriasis versicolor, scabies, secondary bacterial infection, dermatophytosis, Varicella virus infection, verruca vulgaris)</td>
</tr>
<tr>
<td>Inflammatory/immune dermatoses (alopecia, chronic bullous disease of childhood, dermatomyositis, lupus erythematosus, psoriasis vulgaris, vitiligo)</td>
</tr>
<tr>
<td>Reactive dermatoses (acute urticaria)</td>
</tr>
<tr>
<td>Tumors (epidermal nevus, hemangioma, keloid, Langerhans cell histiocytosis, milia, pyogenic granuloma)</td>
</tr>
<tr>
<td>Miscellaneous (acne vulgaris, erythema dyschromium perstans, keratosis pilaris, milia, pityriasis rubra, post-inflamatory hyperpigmentation, prurigo nodularis)</td>
</tr>
</tbody>
</table>

*since 4 participants were diagnosed with 2 skin diseases

Effect on QOL based on IKPaB scores

Figure 2. Percentage distribution of participants according to effect on QOL based on IKPaB scores.

Table 5. Multiple linear regression coefficients for IKPaB scores using age, gender, and duration of skin disease as predictors

<table>
<thead>
<tr>
<th>Predictor variable</th>
<th>Coefficient</th>
<th>SE</th>
<th>T stat</th>
<th>P-value</th>
<th>Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (in years)</td>
<td>0.016</td>
<td>0.059</td>
<td>-0.666</td>
<td>0.79</td>
<td>-0.100, 0.131</td>
</tr>
<tr>
<td>Females</td>
<td>0.238</td>
<td>0.435</td>
<td>0.547</td>
<td>0.59</td>
<td>-0.619, 1.095</td>
</tr>
<tr>
<td>Duration of skin disease (in days)</td>
<td>-0.001</td>
<td>0.000</td>
<td>3.342</td>
<td>0.14</td>
<td>-0.244, -0.011</td>
</tr>
</tbody>
</table>
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Cultural adaptation of the translation showed some cultural-specific differences among Filipino children, namely lack of widespread engagement in sports and their own interpretation of school time and holiday season. Previous validation studies also reported doing similar cultural adaptation procedures (Bulgarian,14 Cantonese,15 Dutch,16 Malaysian,17 and Mexican,18 and Turkish19).

The sample size in this study (n = 288) was larger than the sample sizes of most previous validation studies (ranging from 6 to 379).7 However, it was conducted only in one public tertiary hospital. A multi-center study involving other settings such as private hospitals or community setting would provide a better representation of the Filipino population.

The IKPaB showed comparable construct validity to the initial UK validation study of the CDLQI (comparing children with skin disease to normal children and children with other chronic disease)5 and the validation of the Cantonese version in Hongkong (comparing children with pityriasis rosea to those with no skin disease).20 However, there was a small group of outliers in the control group in this study (n = 9) who did not have skin diseases on physical examination but who had high IKPaB scores, indicating a very large to extremely large effect on their quality of life. A possible reason is that they misunderstood the instructions and considered a previous skin disease as still part of symptoms within the past week.

The negative correlation (rho= -0.300, P-value=0.000) between IKPaB and PedsQL is expected since they have opposite scoring systems. However, the weak correlation (less than 0.4) may be due to the fact that the PedsQL is a generic tool and not specific to skin diseases. It also reflects changes in quality of life due to other non-dermatologic reasons. In contrast, previous validation studies conducted in children with specific skin diseases used disease-specific criterion questionnaires – such as Cardiff Acne Disability Index (CADI), 21,22 and Childhood Atopic Dermatitis Impact Scale (CADIS)23 – as gold standards, and had good criterion validity.

Our findings of acceptable internal consistency reliability (α= 0.87) is congruent with previous studies showing values ranging from 0.82 to 0.92, all above the minimum value for good internal consistency (0.70). This indicates that the homogeneity of the index and the interrelatedness of the different items were maintained in the translated Filipino CDLQI.

This study found no correlation between IKPaB scores and duration of skin disease, sex and age of participants. Similarly, there were no sex nor age differences in a previous Dutch validation study of pediatric patients with vitiligo16 and a Turkish validation study of children with skin diseases.19 In contrast, there was strong correlation between the child’s age and the CDLQI scores (r = 0.41; p = 0.044) in a Portuguese validation study on children with vitiligo. They found the median CDLQI score to be significantly higher in adolescents aged 15 years and older (median = 11, interquartile range = 4.75–14.25, p = 0.04).24 This may signify the greater impact of a depigmenting skin disease such as vitiligo during the age wherein self-identity is critical, and that this is not gender-dependent. This same study, however, found no difference between males and females (p = 0.219). A meta-analysis showing that scabies, an acute skin infestation, had the highest IKPaB scores and lowest quality of life,8 is in agreement with our findings. This shows that it is not just disease chronicity that determines QoL, but also the intensity of symptoms.

CONCLUSION AND RECOMMENDATIONS

The study has shown that the IKPaB, is a reliable and valid Filipino translation of the CDLQI text version in terms of face validity, construct validity, and internal consistency reliability. There is a need to conduct further criterion validity testing using skin disease-specific QoL questionnaires. We recommend that IKPaB be used regularly in clinics for outcome assessment and management of skin diseases for 4- to 16-year-old Filipinos. It should be tested further in disease-specific interventional studies to monitor improvement in QoL.

Statement of Authorship

Primary author - PKNGC and KAZR did the data collection. All authors did data analysis and approved the final version submitted.

Author Disclosure

All authors declared no conflicts of interest.

Funding Source

No outsource funding was made; primary author shouldered all expenses.

REFERENCES


APPENDIX

Final version IKPaB

INDEKS NG KALIDAD NG BUHAY PANG-DERMATOLOHIYA NG MGA BATA

<table>
<thead>
<tr>
<th>Participant Code:</th>
<th>Sakit sa balat:</th>
<th>IKPaB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edad:</td>
<td>Petsa:</td>
<td></td>
</tr>
</tbody>
</table>

PANUTO: Layunin ng palatanungang ito na sukatin kung gaano ka naapektuhan ng problema mo sa balat.
I-TSEK √ lamang ang kahon ng iyong sagot para sa bawat tanong.

1. Noong huling pitong araw, gaano kakati, kahapdi o kasakit ang iyong balat?
   - Sobra sobra
   - Masyado
   - Kaunti lang
   - Hindi kailanman
   - Hindi naaangkop (N/A)

2. Noong huling pitong araw, gaano ka naging mahiyain o naging malungkot dahil sa iyong balat?
   - Sobra sobra
   - Masyado
   - Kaunti lang
   - Hindi kailanman
   - Hindi naaangkop (N/A)

3. Noong huling pitong araw, gaano naapektuhan ng iyong balat ang pakikipagkaibigan mo?
   - Sobra sobra
   - Masyado
   - Kaunti lang
   - Hindi kailanman
   - Hindi naaangkop (N/A)

4. Noong huling pitong araw, gaano ka nagbago o nagsuot ng kakaiba o espesyal na damit/sapatos dahil sa iyong balat?
   - Sobra sobra
   - Masyado
   - Kaunti lang
   - Hindi kailanman
   - Hindi naaangkop (N/A)

5. Noong huling pitong araw, gaano naapektuhan ng iyong problema sa balat ang iyong paglabas-labas, paglalaro o ang paggawa ng mga hiling mo?
   - Sobra sobra
   - Masyado
   - Kaunti lang
   - Hindi kailanman
   - Hindi naaangkop (N/A)

6. Noong huling pitong araw, gaano mo iniwasan ang paglangoy o iba pang isports dahil sa problema mo sa balat?
   - Sobra sobra
   - Masyado
   - Kaunti lang
   - Hindi kailanman
   - Hindi naaangkop (N/A)

7. Noong huling pitong araw, may pasok ka ba sa eskwela?
   - √ OO → sagutan ang LETTER A
   - WALA dahil bakasyon (summer break, sembreak, o holiday) → sagutan ang LETTER B

   A. Kung nasa eskwelahan ka noong nakaraang linggo, gaano naapektuhan ng problema mo sa balat ang iyong mga gawaing pang-eskewla?
      - Sobra sobra
      - Masyado
      - Kaunti lang
      - Hindi kailanman
      - Hindi naaangkop (N/A)

   B. Kung walang pasok sa eskwela dahil BAKASYON (summer, sembreak, pasko), gaano naapektuhan ng problema mo sa balat ang pagpapakasaya mo sa bakasyon?
      - Sobra sobra
      - Masyado
      - Kaunti lang
      - Hindi kailanman
      - Hindi naaangkop (N/A)

8. Noong huling pitong araw, gaano naging problema ang paggamot sa iyong balat?
   - Sobra sobra
   - Masyado
   - Kaunti lang
   - Hindi kailanman
   - Hindi naaangkop (N/A)

9. Noong huling pitong araw, gaano naapektuhan ang tulog mo ng iyong problema sa balat?
   - Sobra sobra
   - Masyado
   - Kaunti lang
   - Hindi kailanman
   - Hindi naaangkop (N/A)

10. Noong huling pitong araw, gaano naging problema ang paggamot sa iyong balat?
    - Sobra sobra
    - Masyado
    - Kaunti lang
    - Hindi kailanman
    - Hindi naaangkop (N/A)

Siguraduhin lamang na nasagutan mo ang BAWAT tanong. Salamat.

© M.S. Lewis-Jones, A.Y. Finlay, Mayo 1993. Ito ay hindi dapat kopyahin ng walang pahintulot ng mga may-akda.